DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 3, 2014

Alvimedica
c/o Lori Adels
Experien Group, LLC
755 N Mathilda Avenue, Suite #100
Sunnyvale, CA 94085

Re: K141529
Trade/Device Name: Alviguide™ Blue+ Interventional Cardiology Guiding Catheter and Alguide™ Endovascular Guiding Catheter
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQY
Dated: October 31, 2014
Received: November 3, 2014

Dear Ms. Adels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Alviguide™ Blue+ Interventional Cardiology Guiding Catheter, Alguide™ Endovascular Guiding Catheter

Indications for Use *(Describe)*
The Alviguide™ Blue+ Interventional Cardiology Guiding Catheter is intended for use in the intravascular introduction of interventional/diagnostic devices into the coronary vascular system.

The Alguide™ Endovascular Guiding Catheter is intended for use in the intravascular introduction of interventional/diagnostic devices into the peripheral vascular system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

510(k) Notification K 141529

GENERAL INFORMATION

Applicant:

Alvimedica Tıbbi Ürünler Sanayi ve Dış Ticaret A.Ş.
İstanbul Trakya Serbest Bölgesi
Ferhatpaşa Mahallesi Atatürk Bulvarı
Manolya Sokak No:7
34540 Çatalca, İstanbul
Turkey
Phone: +90 212 786 60 80
FAX: +90 212 786 60 90

Contact Person:

Lori E. Adels, Ph.D
Regulatory Consultant for Alvimedica
Experien Group, LLC
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085
U.S.A.
Phone: (408) 400-0856 ext. 112
FAX: (408) 400-0865

Date Prepared: June 6, 2014

DEVICE INFORMATION

Trade Name:

Alviguide™ Blue+ Interventional Cardiology Guiding Catheter
Alguide™ Endovascular Guiding Catheter

Classification Name:

Percutaneous catheter

Generic/Common Name:

Guide catheter

Classification:

Class II per 21 CFR§870.1250

Product Code:

DQY

510(k) SUMMARY

PREDICATE DEVICES

- Medtronic 5F Sherpa Active NX Guide Catheter (K062420)
- Medtronic 6F Launcher Guide Catheter
  [Medtronic 6F Z3 Guide Catheter (K021256)]
- Medtronic 7F Launcher Guide Catheter (K022764)
- Medtronic 8F Launcher Guide Catheter (K023402)
- Merit Medical Systems Concierge Guiding Catheter
  [VasCon LLC Polaris Guiding Catheter (K043387)]

INDICATIONS FOR USE

The Alviguide™ Blue+ Interventional Cardiology Guiding Catheter is intended for use in the intravascular introduction of interventional/diagnostic devices into the coronary vascular system.

The Alguide™ Endovascular Guiding Catheter is intended for use in the intravascular introduction of interventional/diagnostic devices into the peripheral vascular system.

PRODUCT DESCRIPTION

The Alviguide™ Blue+ and Alguide™ Guide Catheters are sterile, non-pyrogenic, single lumen catheters with a tri-layer catheter body construction consisting of a polymer inner layer and a radiopaque outer layer surrounding a stainless steel wire braid, and a soft tip at the distal end. The catheters are for single-use only.

The Alviguide™ Blue+ and Alguide™ Guide Catheters are provided in a variety of distal shape configurations and are available in Fr Sizes 5, 6, 7 and 8 and lengths of 45, 60, 65 and 80cm (Alguide™), and 100cm (Alviguide™ Blue+ and Alguide™).

TECHNOLOGICAL CHARACTERISTICS

The indication for use, design and materials used in the Alviguide Blue+ and Alguide Guide Catheters are similar to those of the predicate guide catheters.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Alviguide Blue+ and Alguide Guide Catheters. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Alviguide Blue+ and Alguide Guide Catheters are substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary bench and clinical testing was conducted on the Alviguide Blue+ Guide Catheters to support a determination of substantial equivalence to the predicate devices.

Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Visual Inspection
- Dimensional Verification
- Catheter Sheath Introducer Withdrawal Force
- Hub Leakage
- Kink Diameter and Force
- Tensile Strength
- Radiopacity
- Torque Testing
- Packaging integrity (Visual inspection, seal strength test)
- Sterilization (EO sterilization evaluation, EO residuals, endotoxin)

Biocompatibility Testing Summary:

Biocompatibility testing was conducted in compliance with ISO 10993-1, for externally communicating devices with limited exposure (<24 hours) to circulating blood, and included:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hemocompatibility
- Material Mediated Pyrogen

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Alviguide Blue+ and Alguide Guide Catheters meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Alviguide Blue+ and Alguide Guide Catheters do not raise new questions of safety or effectiveness when compared to the predicate devices.

CONCLUSION

Based on the similar indication, design and materials, and the results of the bench testing, the Alviguide Blue+ Interventional Cardiology Guiding Catheter and Alguide Endovascular Guiding Catheter are considered substantially equivalent to the predicate devices listed above.

SUMMARY

The Alviguide Blue+ Interventional Cardiology Guiding Catheter and the Alguide Endovascular Guiding Catheter are substantially equivalent to the predicate devices.